

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently amended). A multi-component pharmaceutical dosage form for retaining and selectively releasing a drug substance to provide a controlled drug release profile in a gastrointestinal environment, comprising:

a body having a base wall and a first skirt wall axially extending in a first direction from said base wall and terminating in a first rim, said body defining a first cavity having a first mouth opening; and

a first film fixedly attached to the first rim outside of the at least one cavity and closing the first mouth opening, wherein the first film is substantially planar relative to the first mouth opening and a thickness of the first film is substantially thinner than a thickness of the first skirt wall and wherein the film is configured to be directly adjacent the first mouth opening;

wherein at least one of the first film, the body, or an attachment between the first film and the first rim is configured to dissolve or otherwise breach within the gastrointestinal environment to expose the at least one cavity to the gastrointestinal environment.

2. (Currently amended). A multi-component pharmaceutical dosage form according to claim 1 wherein the body and/or the first film is made of materials ~~such that the dosage form opens to release the drug substance~~ configured dissolve or otherwise breach in the gastro-intestinal gastrointestinal environment.

3. (Previously presented). A multi-component pharmaceutical dosage form according to claim 1 wherein the first film is fixedly attached to the body by a weld.

4. (Original). A multi-component pharmaceutical dosage form according to claim 3 wherein the weld is an ultrasonic weld.

5. (Currently amended). A multi-component pharmaceutical dosage form for retaining and selectively releasing a drug substance to provide a controlled drug release profile in a gastrointestinal environment, comprising:

a body having a base wall and a first skirt wall axially extending in a first direction from said base wall and terminating in a first rim, said body defining a first cavity having a first mouth opening; and

a first film fixedly attached to the first rim outside of the at least one cavity and closing the first mouth opening;

wherein the body further includes a ledge formed on the first skirt wall between the base wall and the first rim, the dosage form further including a second film fixedly attached to the ledge inside of the first cavity;

wherein at least one of the first film, the body, or an attachment between the first film and the first rim is configured to dissolve or otherwise breach within the gastrointestinal environment to expose the at least one cavity to the gastrointestinal environment.

6. (Currently amended). A multi-component pharmaceutical dosage form for retaining and selectively releasing a drug substance to provide a controlled drug release profile in a gastrointestinal environment, comprising:

a body having a base wall and a first skirt wall axially extending in a first direction from said base wall and terminating in a first rim, said body defining a first cavity having a first mouth opening; and

a first film fixedly attached to the first rim outside of the at least one cavity and closing the first mouth opening

wherein the body includes a second skirt wall axially extending in a second direction opposite the first direction from the base wall and terminating in a second rim, said body defining a second cavity having a second mouth opening, the dosage form further including a second film fixedly attached to the second rim outside of the second cavity;

wherein at least one of the first film, the second film, the body, an attachment between the first film and the first rim, or an attachment between the second film and the second rim is configured to dissolve or otherwise breach within the gastrointestinal environment to expose the at least one cavity or the second cavity to the gastrointestinal environment.

7. (Previously presented). A multi-component pharmaceutical dosage form according to claim 6 wherein at least one of the first and/or second film is convex relative to the respective first and/or second mouth opening.

8. (Previously presented). A multi-component pharmaceutical dosage form according to claim 6 wherein at least one of the first and/or second film is substantially planar relative to the respective first and/or second mouth opening.

9. (Currently amended). A multi-component pharmaceutical dosage form for retaining and selectively releasing a drug substance to provide a controlled drug release profile in a gastrointestinal environment, comprising:

a body having a base wall and a first skirt wall axially extending in a first direction from said base wall and terminating in a first rim, said body defining a first cavity having a first mouth opening; and

a first flexible film fixedly attached to the first rim outside of the at least one cavity and closing the first mouth opening

wherein the body includes a second skirt wall axially extending in the first direction from the base wall and terminating in a second rim, said body defining a second cavity having a second mouth opening, the first film fixedly attached to both the first and second rims outside the first and second cavities, closing the first and second cavities;

wherein at least one of the first film, the body, or an attachment between the first film and the first rim is configured to dissolve or otherwise breach within the gastrointestinal environment to expose the at least one cavity to the gastrointestinal environment.

10. (Previously presented). A multi-component pharmaceutical dosage form according to claim 9 wherein the first and second cavities are adjacent and are divided from each other by a common skirt wall and the first and second rims are substantially coplanar.

11. (Previously presented). A multi-component pharmaceutical dosage form according to claim 1 wherein the first film comprises a first film layer and second film layer at least

partially spaced apart from the first film layer and defining a compartment configured to retain a drug substance between said first and second film layers.

12. (Previously presented). A multi-component pharmaceutical dosage form according to claim 11 wherein the first film layer and the second film layer are both fixedly attached to the first rim outside of the first cavity by a weld.

13. (Currently amended). A multi-component pharmaceutical dosage form according to claim 11 wherein the ~~second~~ first film layer is disposed between the first second film layer and the base wall and the ~~first~~ second film layer is convex relative to the first mouth opening.

14. (Cancelled).

15. (Previously presented). A dosage form according to claim 1 wherein the body is a first body and the base wall is a first base wall, the dosage form further including a second body having a second base wall and a second skirt wall axially extending from said base wall and terminating in a second rim, said second body defining a second cavity having a second mouth opening, wherein the first and second bodies are connected to each other such that the second rim surrounds the first rim and the first film is disposed between and separates the first cavity from the second cavity.

16. (Previously presented). A dosage form according to claim 15 wherein the second body is a capsule shell and the first body is configured as a closure for the capsule shell such that the first and second mouth openings are facing toward one another.

17. (Previously presented). A dosage form according to claim 16 wherein the first body fits into the second mouth opening via a plug and socket relationship.

18. (Previously presented). A dosage form according to claim 16 further comprising another capsule shell defining a third cavity, having a third mouth opening wherein the first body is further configured as a closure for the third mouth opening.

19. (Previously presented). A dosage form according to claim 18 wherein the first body fits into the third mouth opening via a in a plug and socket relationship.

20. (Cancelled).

21. (Previously presented). A dosage form comprising a substantially linear arrangement of:

a first capsule shell defining a first cavity and having a first mouth opening,
a second body fitting into the first mouth opening via a plug and socket relationship, the second body having a second cavity therein having a second mouth opening which is closed by a film fixedly attached to the second mouth opening outside of the second cavity, such that when the second body is fitted into the first mouth opening the film is disposed between the first and second cavities,
and a second capsule shell defining a third cavity and having a third mouth opening into which the second body fits in plug and socket relationship.

22. (Previously presented). A dosage form according to claim 16 wherein the capsule shell is made of an immediate release polymer.

23. (Previously presented). A dosage form according to claim 18 wherein the capsule shells are both made of immediate release polymer.
24. (Previously presented). A dosage form according to claim 16 wherein the first film comprises an immediate release polymer.
25. (Previously presented). A dosage form according to claim 18 wherein the capsule shells and the first film are immediate release polymers.
26. (Previously presented). A dosage form according to claim 16 wherein the first and second bodies are connected together by a weld.
27. (Cancelled).
28. (Previously presented). A dosage form according to claim 24 wherein the immediate-release film comprises hydroxyethyl cellulose, low molecular weight hydroxypropylcellulose or low-substituted hydroxypropyl cellulose.
29. (Previously presented). A dosage form according to claim 1 wherein the first film is 20-300 micron thick.
30. (Previously presented). A dosage form according to claim 1 coated with a polymeric coating.
31. (Original). A dosage form according to claim 30 wherein the coating comprises a delayed or pulsed release polymer which dissolves or is otherwise breached in an environment of defined pH.

32. (Original). A dosage form according to claim 31 wherein said polymer is an enteric polymer.

33. (Cancelled).

34. (Previously presented). A dosage form according to claim 1 wherein the body comprises a delayed release polymer and the first film comprises an immediate release polymer.

35. (Previously presented). A dosage form according to claim 5 wherein the first film comprises an immediate release polymer and the second film comprises a delayed release polymer.

36. (Cancelled).

37. (Currently amended). A body suitable for use in a pharmaceutical dosage form comprising a base wall, a first wall extending from the base wall in a first direction and defining a first cavity having a mouth opening with a rim ~~and~~ adapted for connecting a polymer film thereto outside of the first cavity for closing the first cavity, and a second wall extending from the base wall in a second direction, opposite the first direction, and defining a second cavity having a mouth opening with a rim ~~and~~ adapted for connecting a polymer film thereto outside of the second cavity for closing the second cavity.

38. (Original). A body according to claim 37 comprising a delayed release polymer or an immediate release polymer.

39. (Original). A body according to claim 38 wherein the polymer comprises a delayed release polymer.

40. (Cancelled).

41. (Previously presented). A process for the preparation of a dosage form according to claim 6 comprising the following steps:

1. Forming the body by injection molding of a polymer
2. Optionally applying a polymer coat to the body.
3. Filling the first cavity with the drug substance
4. Closing the first cavity with the first film
5. Filling the second cavity with the same or different drug substance
6. Closing the second cavity.

42. (Previously presented). A multi-component dosage form according to claim 1, wherein the base wall includes a thinned region having a wall thickness less than the remainder of the base wall.

43. (Previously presented). A multi-component dosage form according to claim 1, wherein the body includes a second skirt wall axially extending in the first direction from the base wall and terminating in a second rim, said body defining a second cavity having a second mouth opening, the dosage form further comprising a second film fixedly attached to the second rim outside the second cavity.

44. (Previously presented). A multi-component dosage form according to claim 43 wherein the first film is made from an intermediate release polymer and wherein the second film is made from a polymer having a delayed release polymer.

45 (Previously presented). A multi-component dosage form according to claim 1 wherein the body is a first body that further includes a second skirt wall axially extending in the first direction from the base wall and terminating in a second rim, said body defining a second cavity having a second mouth opening, the dosage form further comprising:

a second body having a base wall and a skirt wall axially extending therefrom and terminating in a rim defining a second body cavity;

wherein the first and second bodies are connected to each other such that the rim of the second body surrounds the first and second rims of the first and second cavities of the first body; and

wherein the first film is disposed between the first cavity of the first body and the cavity of the second body.

46. (Previously presented). A multi-component form according to claim 1 wherein the first film is a laminate film comprising a plurality of separate layers.

47. (Previously presented). The multi-component pharmaceutical dosage form according to claim 1, wherein a ratio of the thickness of the skirt wall to the thickness of the film is greater than approximately 3 and less than approximately 20.

48. (Previously presented). The multi-component pharmaceutical dosage form according to claim 1, wherein a ratio of the thickness of the skirt wall to the thickness of the film is greater than approximately 2 and less than approximately 25.

49. (Previously presented). The multi-component pharmaceutical dosage form according to claim 1, wherein the film thickness is greater than approximately 20 microns and less than approximately 300 microns.

50. (Currently amended). A multi-component pharmaceutical dosage form for retaining and selectively releasing a drug substance to and provide a controlled drug release profile in a gastrointestinal environment, comprising:

a body having a base wall and a first skirt wall axially extending in a first direction from said base wall and terminating in a first rim, said body defining a first cavity having a first mouth opening; and

a first laminate film fixedly attached to the first rim outside of the at least one cavity and closing the first mouth opening;

wherein at least one of the first laminate film, the body, or an attachment between the first laminate film and the first rim is configured to dissolve or otherwise breach within the gastrointestinal environment to expose the at least one cavity to the gastrointestinal environment.

51 (Previously presented). A multi-component pharmaceutical dosage form for retaining and selectively releasing a drug substance to provide a controlled drug release profile in a gastrointestinal environment, comprising:

a body having a base wall and a first skirt wall axially extending in a first direction from said base wall and terminating in a first rim, said body defining a first cavity having a first mouth opening; and

a first convex film fixedly attached to the first rim outside of the at least one cavity and closing the first mouth opening.

52. (Currently amended). A multi-component pharmaceutical dosage form for retaining and selectively releasing a drug substance to provide a controlled drug release profile in a gastrointestinal environment, comprising:

a body having a base wall and a first skirt wall axially extending in a first direction from said base wall and terminating in a first rim, said body defining a first cavity having a first mouth opening; and

a first film fixedly attached to the first rim outside of the at least one cavity via a welded joint between the first film and the first rim, the first film closing the first mouth opening;

wherein at least one of the first film, the body, or an attachment between the first film and the first rim is configured to dissolve or otherwise breach within the gastrointestinal environment to expose the at least one cavity to the gastrointestinal environment.